General Assembly

Raised Bill No. 295

February Session, 2004

LCO No. **1379**

01379_____PRI

Referred to Committee on Program Review and Investigations

Introduced by:
(PRI)

AN ACT IMPLEMENTING THE RECOMMENDATIONS OF THE LEGISLATIVE PROGRAM REVIEW AND INVESTIGATIONS COMMITTEE RELATIVE TO PHARMACY BENEFITS.

Be it enacted by the Senate and House of Representatives in General Assembly convened:

Section 1. Section 17b-274d of the general statutes, as amended by section 19 of public act 03-2, section 63 of public act 03-278 and section 83 of public act 03-3 of the June 30 special session, is repealed and the following is substituted in lieu thereof (*Effective July 1, 2004*):

(a) Pursuant to 42 USC 1396r-8, there is established a Medicaid Pharmaceutical and Therapeutics Committee within the Department of Social Services. **[**Said committee shall convene on or before March 31, 2003.**]** The Commissioner of Social Services shall report monthly, in accordance with section 11-4a, to the joint standing committees of the General Assembly having cognizance of matters relating to appropriations and the budgets of state agencies and human services and to the Legislative Program Review and Investigations Committee on the activities of the Medicaid Pharmaceutical and Therapeutics Committee. The commissioner shall continue to make such monthly reports until such time as a preferred drug list that includes three

classes of drugs, including proton pump inhibitors and two other classes of drugs as determined by the commissioner, has been adopted in accordance with subsection (e) of this section.

(b) The Medicaid Pharmaceutical and Therapeutics Committee shall be comprised as specified in 42 USC 1396r-8 and shall consist of fourteen members appointed by the Governor. Five members shall be physicians licensed pursuant to chapter 370, including one general practitioner, one pediatrician, one geriatrician, one psychiatrist and one specialist in family planning, four members shall be pharmacists licensed pursuant to chapter 400j, two members shall be visiting nurses, one specializing in adult care and one specializing in psychiatric care, one member shall be a clinician designated by the Commissioner of Mental Health and Addiction Services, one member shall be a representative of pharmaceutical manufacturers and one member shall be a consumer representative. The committee may, on an ad hoc basis, seek the participation of other state agencies or other interested parties in its deliberations. The members shall serve for terms of two years from the date of their appointment. Members may be appointed to more than one term. The Commissioner of Social Services, or the commissioner's designee, shall convene the committee following the Governor's designation of appointments. The administrative staff of the Department of Social Services shall serve as staff for said committee and assist with all ministerial duties. The Governor shall ensure that the committee membership includes Medicaid participating physicians and pharmacists, with experience serving all segments of the Medicaid population.

(c) Committee members shall select a chairperson and vice-chairperson from the committee membership on an annual basis.

(d) The committee shall meet at least quarterly, and may meet at other times at the discretion of the chairperson and committee membership. The committee shall comply with all regulations adopted by the department, including notice of any meeting of the committee,

pursuant to the requirements of chapter 54.

(e) **[**On or before July 1, 2003, the**]** The Department of Social Services, in consultation with the Medicaid **[**and**]** Pharmaceutical and Therapeutics Committee, shall adopt a preferred drug list for use in the Medicaid, state-administered general assistance, HUSKY Plan, Part A, HUSKY Plan, Part B, Connecticut AIDS drug assistance and ConnPACE programs. To the extent feasible, the department shall review all drugs included in the preferred drug list at least every twelve months, and may recommend additions to, and deletions from, the preferred drug list, to ensure that the preferred drug list provides for medically appropriate drug therapies for Medicaid, state-administered general assistance, HUSKY Plan, Part A, HUSKY Plan, Part B, Connecticut AIDS drug assistance and ConnPACE patients. For the fiscal year ending June 30, 2004, such drug list shall be limited to use in the Medicaid and ConnPACE programs and cover three classes of drugs, including proton pump inhibitors and two other classes of drugs determined by the Commissioner of Social Services. **[**The commissioner shall notify the joint standing committees of the General Assembly having cognizance of matters relating to human services and appropriations of the classes of drugs on the list by January 1, 2004.**]** For the fiscal year ending June 30, 2005, such drug list shall be expanded to include all eligible classes of drugs as determined by the Department of Social Services in consultation with the Medicaid Pharmaceutical and Therapeutics Committee.

(f) Except for mental-health-related drugs and antiretroviral drugs, reimbursement for a drug not included in the preferred drug list is subject to prior authorization.

(g) The Department of Social Services shall publish and disseminate the preferred drug list to all Medicaid providers in the state.

(h) The committee shall ensure that the pharmaceutical manufacturers agreeing to provide a supplemental rebate pursuant to 42 USC 1396r-8(c) have an opportunity to present evidence supporting

inclusion of a product on the preferred drug list unless a court of competent jurisdiction, in a final decision, determines that the Secretary of Health and Human Services does not have authority to allow such supplemental rebates, provided the inability to utilize supplemental rebates pursuant to this subsection shall not impair the committee's authority to maintain a preferred drug list. Upon timely notice, the department shall ensure that any drug that has been approved, or had any of its particular uses approved, by the United States Food and Drug Administration under a priority review classification, will be reviewed by the Medicaid Pharmaceutical and Therapeutics Committee at the next regularly scheduled meeting. To the extent feasible, upon notice by a pharmaceutical manufacturer, the department shall also schedule a product review for any new product at the next regularly scheduled meeting of the Medicaid Pharmaceutical and Therapeutics Committee.

(i) Factors considered by the department and the Medicaid Pharmaceutical and Therapeutics Committee in developing the preferred drug list shall include, but not be limited to, clinical efficacy, safety and cost effectiveness of a product.

(j) The Medicaid Pharmaceutical and Therapeutics Committee may also make recommendations to the department regarding the prior authorization of any prescribed drug covered by Medicaid in accordance with the plan developed and implemented pursuant to section 17b-491a.

(k) Medicaid recipients may appeal any department preferred drug list determinations utilizing the Medicaid fair hearing process administered by the Department of Social Services established pursuant to chapter 54.

[(l) The provisions of this section shall apply to the state-administered general assistance program.**]**

(l) The Commissioner of Social Services shall contract with a

pharmacy benefits organization or a single entity qualified to negotiate with pharmaceutical manufacturers for supplemental rebates, available pursuant to 42 USC 1396r-8(c), for drugs listed on the preferred drug list established pursuant to subsection (e) of this section.

Sec. 2. (NEW) (*Effective July 1, 2004*) The Commissioner of Social Services, upon the renewal of a contract between the Department of Social Services and a managed care organization providing comprehensive medical services to the HUSKY Plan, Part A, or HUSKY Plan, Part B, shall assign and consolidate all responsibility for the administration of pharmacy benefits available under the HUSKY Plan, Parts A and B to the department. The administration of pharmacy benefits available under the HUSKY Plan, Parts A and B shall be consolidated with the fee-for-service pharmacy programs administered by the department.

Sec. 3. Section 17b-363a of the general statutes, as amended by section 1 of public act 03-116 and section 146 of public act 03-6 of the June 30 special session, is repealed and the following is substituted in lieu thereof (*Effective July 1, 2004*):

(a) Each long-term care facility shall return to the vendor pharmacy which shall accept, for repackaging and reimbursement to the Department of Social Services, drug products that were dispensed to a patient and not used if such drug products are (1) prescription drug products that are not controlled substances, (2) sealed in individually packaged units, (3) returned to the vendor pharmacy within the recommended period of shelf life for the purpose of redispensing such drug products, (4) determined to be of acceptable integrity by a licensed pharmacist, and (5) oral and parenteral medication in single-dose sealed containers approved by the federal Food and Drug Administration, topical or inhalant drug products in units of use containers approved by the federal Food and Drug Administration or parenteral medications in multiple-dose sealed containers approved by

the federal Food and Drug Administration from which no doses have been withdrawn.

(b) Notwithstanding the provisions of subsection (a) of this section:

(1) If such drug products are packaged in manufacturer's unit-dose packages, such drug products shall be returned to the vendor pharmacy for redispensing and **[**reimbursement to**]** such vendor pharmacy shall reimburse the Department of Social Services if such drugs may be redispensed for use before the expiration date, if any, indicated on the package.

(2) If such drug products are repackaged in manufacturer's unit-dose or multiple-dose blister packs, such drug products shall be returned to the vendor pharmacy for redispensing and **[**reimbursement to**]** such vendor pharmacy shall reimburse the Department of Social Services if: (A) **[**the**]** The date on which such drug product was repackaged, such drug product's lot number and expiration date are indicated clearly on the package of such repackaged drug; (B) ninety days or fewer have elapsed from the date of repackaging of such drug product; and (C) a repackaging log is maintained by the pharmacy in the case of drug products repackaged in advance of immediate needs.

(3) No drug products dispensed in a bulk dispensing container may be returned to the vendor pharmacy.

(c) Each long-term care facility shall establish procedures for the return of unused drug products to the vendor pharmacy from which such drug products were purchased.

(d) A vendor pharmacy providing drug products to a long-term care facility shall provide such drug products in packaging that facilitates return of unused drug products to the vendor pharmacy in accordance with subsections (a) and (b) of this section.

[(d)**]** (e) The Department of Social Services (1) shall reimburse **[**to**]**

the vendor pharmacy for the reasonable cost of services incurred in the operation of this section, as determined by the commissioner, and (2) may establish procedures, if feasible, for **[**reimbursement to**]** reimbursing non Medicaid payors for drug products returned pursuant to this section.

[(e)**]** (f) The Department of Agriculture and Consumer Protection, in consultation with the Department of Social Services, shall adopt regulations, in accordance with the provisions of chapter 54, which shall govern the repackaging and labeling of drug products returned pursuant to subsections (a) and (b) of this section. The Department of Agriculture and Consumer Protection shall implement the policies and procedures necessary to carry out the provisions of this section until January 1, 2002, while in the process of adopting such policies and procedures in regulation form, provided notice of intent to adopt the regulations is published in the Connecticut Law Journal within twenty days after implementation.

[(f)**]** (g) Any long-term care facility that violates or fails to comply with the provisions of this section shall be fined **[**thirty**]** one thousand dollars for each incidence of noncompliance. The **[**commissioner**]** Commissioner of Social Services may offset payments due a facility to collect the penalty. Prior to imposing any penalty pursuant to this subsection, the commissioner shall notify the long-term care facility of the alleged violation and the accompanying penalty and shall permit such facility to request that the department review its findings. A facility shall request such review **[**within**]** not later than fifteen days **[**of**]** after receipt of the notice of violation from the department. The department shall stay the imposition of any penalty pending the outcome of the review. The commissioner may impose a penalty upon a facility pursuant to this subsection regardless of whether a change in ownership of the facility has taken place since the time of the violation, provided the department issued notice of the alleged violation and the accompanying penalty prior to the effective date of the change in ownership and record of such notice is readily available in a central

registry maintained by the department. Payments of fines received pursuant to this subsection shall be deposited in the General Fund and credited to the Medicaid account.

[(g)**]** (h) The Commissioner of Social Services, in consultation with the pharmacy review panel established in section 17b-362a, as amended, shall update and expand by June 30, 2003, and annually thereafter, the list of drugs that are included in the drug return program. Such list shall include, but not be limited to, the fifty drugs with the highest average wholesale price that meet the requirements for the program, as established in subsection (a) of this section.

Sec. 4. Subsection (a) of section 17b-491 of the general statutes, as amended by section 14 of public act 03-2, is repealed and the following is substituted in lieu thereof (*Effective July 1, 2004*):

(a) There shall be a "Connecticut Pharmaceutical Assistance Contract to the Elderly and the Disabled Program" which shall be within the Department of Social Services. The program shall consist of payments by the state to pharmacies for the reasonable cost of prescription drugs dispensed to eligible persons minus a copayment charge. The pharmacy shall collect the copayment charge from the eligible person at the time of each purchase of prescription drugs, and shall not waive, discount or rebate in whole or in part such amount. The copayment for each prescription shall be as follows:

(1) Ten dollars for generic prescription drugs if the participant is (A) not married and has an annual income of less than twenty thousand three hundred dollars, or (B) is married and has an annual income that, when combined with the participant's spouse, is less than twenty-seven thousand five hundred dollars.

[(1)**]** (2) Sixteen dollars and twenty-five cents for brand name prescription drugs if the participant is (A) not married and has an annual income of less than twenty thousand three hundred dollars, or (B) is married and has an annual income that, when combined with the

participant's spouse, is less than twenty-seven thousand five hundred dollars.

[(2)**]** (3) Upon the granting of a federal waiver to expand the program in accordance with section 17b-492, as amended, the copayment for brand name prescription drugs shall be twenty dollars for a participant who is (A) not married and has an annual income that equals or exceeds twenty thousand three hundred dollars, or (B) married and has an annual income that, when combined with the participant's spouse, equals or exceeds twenty-seven thousand five hundred dollars.

Sec. 5. (NEW) (*Effective July 1, 2004*) (a) As used in this section:

(1) "Prescription drugs" means (A) legend drugs, as defined in section 20-571 of the general statutes, as amended, (B) any other drugs which by state law or regulation require the prescription of a licensed practitioner for dispensing, except products prescribed for cosmetic purposes as specified in regulations adopted pursuant to section 17b-494 of the general statutes, diet pills, smoking cessation gum, contraceptives, multivitamin combinations, cough preparations and antihistamines, and (C) insulin, insulin syringes and insulin needles;

(2) "State agency" means each state board, authority, commission, department, office, institution, council or other agency of the state, including, but not limited to, each constituent unit of higher education and each public institution of higher education.

(b) On or before October 15, 2004, and annually thereafter, each state agency that purchases prescription drugs shall prepare and submit to the Office of Policy and Management a report that includes: (1) The total amounts spent by the state agency on prescription drugs for the preceding fiscal year, and (2) the total amount of any rebates or credits received by such agency from prescription drug manufacturers, wholesalers or group purchasing organizations of which the state is a participating member. Any state agency with multiple institutions that

purchase prescription drugs shall provide the information required by this section for each institution.

Sec. 6. (NEW) *(Effective July 1, 2004)* (a) For purposes of this section, "state agency" means each state board, authority, commission, department, office, institution, council or other agency of the state, including, but not limited to, each constituent unit of higher education and each public institution of higher education.

(b) The Commissioner of Administrative Services shall require each state agency that obtains drug products through a contract negotiated by the Department of Administrative Services and dispenses such drug products directly to patients to return such drug products that are unused to the vendor pharmacy. The vendor pharmacy shall accept, for repackaging and reimbursement to any such state agency, drug products that were dispensed to a patient and not used if such drug products are (1) prescription drug products that are not controlled substances, (2) sealed in individually packaged units, (3) returned to the vendor pharmacy within the recommended period of shelf life for the purpose of redispensing such drug products, (4) determined to be of acceptable integrity by a licensed pharmacist, and (5) oral and parenteral medication in single-dose sealed containers approved by the federal Food and Drug Administration, topical or inhalant drug products in units of use containers approved by the federal Food and Drug Administration or parenteral medications in multiple-dose sealed containers approved by the federal Food and Drug Administration from which no doses have been withdrawn.

(c) Notwithstanding the provisions of subsection (b) of this section:

(1) If such drug products are packaged in manufacturer's unit-dose packages, such drug products shall be returned to the vendor pharmacy for redispensing and such vendor pharmacy shall reimburse such state agency if such drugs may be redispensed for use before the expiration date, if any, indicated on the package.

(2) If such drug products are repackaged in manufacturer's unit-dose or multiple-dose blister packs, such drug products shall be returned to the vendor pharmacy for redispensing and such vendor pharmacy shall reimburse such state agency if: (A) The date on which such drug product was repackaged, such drug product's lot number and expiration date are indicated clearly on the package of such repackaged drug; (B) ninety days or fewer have elapsed from the date of repackaging of such drug product; and (C) a repackaging log is maintained by the pharmacy in the case of drug products repackaged in advance of immediate needs.

(3) No drug products dispensed in a bulk dispensing container may be returned to the vendor pharmacy.

(c) The Department of Administrative Services shall establish procedures for the return of unused drug products to the vendor pharmacy from which such drug products were purchased.

(d) A state agency that obtains and dispenses drug products, as provided in subsection (b) of this section, shall reimburse the vendor pharmacy for the reasonable cost of services incurred in the operation of this section, as determined by the Commissioner of Administrative Services.

(e) The Department of Agriculture and Consumer Protection, in consultation with the Department of Administrative Services, shall adopt regulations, in accordance with the provisions of chapter 54 of the general statutes, which shall govern the repackaging and labeling of drug products returned pursuant to subsections (b) and (c) of this section. The Department of Agriculture and Consumer Protection shall adopt regulations, in accordance with the provisions of chapter 54 of the general statutes, concerning the repackaging and return of unused drug products.

This act shall take effect as follows:

Section 1	*July 1, 2004*
Sec. 2	*July 1, 2004*
Sec. 3	*July 1, 2004*
Sec. 4	*July 1, 2004*
Sec. 5	*July 1, 2004*
Sec. 6	*July 1, 2004*

Statement of Purpose:

To implement the recommendations of the Legislative Program Review and Investigations Committee's December 2003 study "Pharmacy Benefits and Regulation".

[Proposed deletions are enclosed in brackets. Proposed additions are indicated by underline, except that when the entire text of a bill or resolution or a section of a bill or resolution is new, it is not underlined.]